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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/514,312	02/28/2000	Takahide Kasai	31671-157328RK	8281
26694	7590 08/26/2003			
VENABLE, BAETJER, HOWARD AND CIVILETTI, LLP			EXAMINER	
	P.O. BOX 34385 WASHINGTON, DC 20043-9998		DI NOLA BARON, LILIANA	
			ART UNIT	PAPER NUMBER
·			1615	.26

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)				
. Office Action Summary		09/514,312	KASAI ET AL.				
		Examiner	Art Unit				
		Liliana Di Nola-Baron	1615				
	The MAILING DATE of this communication appears on the cover sheet with the corresp ndence address						
Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM							
 THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). 							
Status							
1)🛛	Responsive to communication(s) filed on <u>11 June 2003</u> .						
2a)⊠	This action is FINAL . 2b) Thi	is action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.							
Disposition of Claims							
4) Claim(s) 45-70 is/are pending in the application.							
	4a) Of the above claim(s) is/are withdrawn from consideration.						
· ·	5) Claim(s) is/are allowed.						
•	6) Claim(s) <u>45-70</u> is/are rejected.						
·	7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or election requirement. Application Papers							
9) The specification is objected to by the Examiner.							
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.							
٠٠,۵	Applicant may not request that any objection to the						
11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.							
If approved, corrected drawings are required in reply to this Office action.							
12)☐ The oath or declaration is objected to by the Examiner.							
Priority under 35 U.S.C. §§ 119 and 120							
13)⊠ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).							
a)⊠ All b)□ Some * c)□ None of:							
1.⊠ Certified copies of the priority documents have been received.							
2. Certified copies of the priority documents have been received in Application No							
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).							
* See the attached detailed Office action for a list of the certified copies not received.							
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).							
a) ☐ The translation of the foreign language provisional application has been received. 15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.							
Attachment(s)							
2) Notic	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449) Paper No(s) _	5) Notice of Informal F	r (PTO-413) Paper No(s) Patent Application (PTO-152)				

Application/Control Number: 09/514,312

Art Unit: 1615

DETAILED ACTION

Receipt of Applicant's amendment, filed on June 11, 2003, is acknowledged.

Claim Rejections - 35 USC § 112

- 1. The following is a quotation of the second paragraph of 35 U.S.C. 112:
 - The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 2. Claims 59-61 and 65-67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 3. Regarding claims 59-61 and 65-67, the phrase "an additional enzyme" renders the claims indefinite, because it is not clear what enzymes are claimed in the process of the invention.

Claim Rejections - 35 USC § 103

- 4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5. Claims 45-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishiguro et al. (U.S. Patent 5,521,089).

Application/Control Number: 09/514,312

Art Unit: 1615

Ishiguro et al. provides a process for producing microcapsules utilizing yeast cell wall comprising glucan, mannan and chitin (See col. 2, lines 35-60). Ishiguro et al. teaches that the yeast cell wall and their components, specifically glucan, mannan and chitin, can be dissolved by enzymes, and the degree of dissolution can determine the physical strength and/or film characteristics, such as the speed of release from the microcapsule, of the material (See col. 3, line 46 to col. 4, line 14). Ishiguro et al. teaches that the optimal pH for many enzymes is 4-9, thus contemplating an acidic environment, and termination of the reaction can be carried out by several methods, including adjustment of pH (See col. 4, lines 15-32). It is the view of the examiner, that in order to adjust the pH to 6 and below, an acid must be added to the reaction mixture. As an alternative method, Ishiguro et al. teaches that the process for producing microcapsules comprises treating yeast cells with alkaline solutions, rather than with enzymes (See col. 3, lines 13-22). Ishiguro et al. teaches that the step of washing the yeast cells can be incorporated in the process (See col. 3, lines 23-24), thus the process disclosed by the patent comprises the step of treating the yeast cells with water, as claimed by Applicant. Ishiguro et al. teaches that the yeast cells treated with an enzyme, which dissolves the cell wall are mixed with a hydrophobic liquid to be confined therein (See col. 3, lines 1-4), thus contemplating the presence of a plasticizer in the coating agent, and encapsulation is carried out by mixing hydrophobic liquid with the yeast dispersion in water using an emulsifier, and optionally pH regulators and water-resisting agents (See col. 5, lines 10-62). Ishiguro et al. teaches that lytic enzymes and other enzymes can be used in the process of the invention (See col. 4, lines 1-3). More specifically, Ishiguro et al. teaches that the yeast cells used in the invention may be subjected to suitable treatments, and components, such as enzymes, protein, amino acid,

Art Unit: 1615

saccharide and nucleic acid, may be extracted by various methods before using said yeast cells (See col. 5, lines 7-17). Thus, the patent contemplates using lytic enzymes, and other proteases or nucleases to eliminate unwanted components. Ishiguro et al. teaches that the microcapsules are used for cosmetics, medicines, food, feeds and chemicals (See col. 5, lines 36-39). In the examples provided, the microcapsules of the invention are coated on paper (See Example 2), thus the surface of a solid material is coated with the coating agent of the invention.

Thus, Ishiguro et al. provides methods for producing coated materials from yeast cell walls, and microcapsules produced by said processes. Ishiguro et al. does not specifically mention that the microcapsules are impermeable to gasses, however, it teaches that the degree of dissolution of the yeast cell walls can determine the physical strength and/or film characteristics of the compositions of the invention, and it is possible to obtain microcapsules, which are resistant to heat and humidity (See col. 4, lines 4-38).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the teachings of Ishiguro et al. to device a process for producing a coated material, and obtain coated materials from the processes of the invention. The expected result would have been a successful method to provide coated materials from yeast cell walls. Because of the teachings of Ishiguro et al., that the degree of dissolution can determine the physical strength and/or film characteristics of the formulations, one of ordinary skill in the art would have a reasonable expectation that the methods and compositions claimed in the instant application would be successful. Therefore the invention as a whole would have been *prima* facie obvious to one of ordinary skill in the art at the time the invention was made.

Application/Control Number: 09/514,312 Page 5

Art Unit: 1615

Response to Arguments

6. Applicant's arguments filed on June 11, 2003 have been fully considered but they are not persuasive.

- 7. Applicant argues that the prior art discloses microcapsules, which do not coat solid surfaces. In response to said argument, it is noted that the coating agent claimed by Applicant can be made of microcapsules. Furthermore, in the examples provided in the patent, the microcapsules of the invention are coated on paper (See Example 2), thus the surface of a solid material is coated with the coating agent of the invention.
- 8. In response to Applicant's argument, that Ishiguro et al. discloses a variety of methods that can be used other than the addition of an acid to terminate its enzymatic reactions, it is noted that adjustment of pH to bring the pH to the desired range 4-9, thus including addition of an acid, is a commonly used technique well known to those of ordinary skill in the art, and the patent clearly provides the teachings that said technique can be used in the art.
- 9. In response to Applicant's argument, that in the examples provided the enzymatic reactions are terminated by treating with a base, it is noted that the examples are only the inventor's best mode. Ishiguro et al. provides the general teachings that the enzymatic reaction can be terminated by adjusting pH, which includes the addition of an acid to the reaction mixture.
- 10. In response to Applicant's argument, that the reference does not suggest or disclose using plasticizers as part of the coating agent, it is noted that Ishiguro et al. teaches that the yeast cells treated with an enzyme, which dissolves the cell wall are mixed with a hydrophobic liquid to be

confined therein (See col. 3, lines 1-4), thus contemplating the presence of a plasticizer in the coating agent.

- 11. Applicant argues that Ishiguro et al. does not suggest or disclose a method comprising treating yeast with an additional enzyme other than one specific for a yeast cell wall substance. In response to said argument, it is noted that Ishiguro et al. teaches that the yeast cells used in the invention may be subjected to suitable treatments, and components, such as enzymes, protein, amino acid, saccharide and nucleic acid, may be extracted by various methods before using said yeast cells (See col. 5, lines 7-17). Thus, the patent contemplates using lytic enzymes, and other proteases or nucleases to eliminate unwanted components.
- 12. In response to Applicant's argument, that Ishiguro et al. does not suggest or disclose a treatment that ruptures the cell walls prior to the treatment with an enzyme, it is noted that pretreatment does not impart any patentability per se, and there is no indication that the pretreatment imparts any additional property to the coating agent of the invention.
- 13. Applicant argues that Ishiguro et al. does not suggest or disclose a process, in which a hydrophobic liquid is absent from a coating material. In response to said argument, it is noted that Ishiguro et al. teaches that the hydrophobic liquid is mixed with the yeast cells only after the treatment of said yeast cells with the enzyme to remove the soluble cell constituents (See col. 3, lines 1-4). With respect to claims 63 and 69, the "comprising" language in the claims allows for the presence of a hydrophobic liquid in the process of the invention. With regard to claims 64 and 70, the burden is shifted to Applicant, to show that mixing the treated cells with a hydrophobic agent would be detrimental to the process claimed in the instant application.

Conclusion

- 14. Claims 45-70 are rejected.
- 15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 703-308-8318. The examiner can normally be reached on Monday through Thursday, 5:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Art Unit: 1615

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234/1235.

Long,

August 10, 2003

THURMAN K. PAGE SUPERVISORY PATENT EXAMINER TECHNOLOGY DENTER 1600